

## REMARKS

Claims 1-17, 19-61, 63, and 75-82 were pending in the application prior to the present amendment. Claims 2, 7-13, 15, 25-31, 35, 36, 38, 40, 41, and 43 were withdrawn from consideration, pursuant to a restriction requirement, leaving claims 1, 3-6, 14, 16, 17, 19-24, 32-34, 37, 39, 42, 44-53, 61, and 63 subject to examination. The objections and rejections are addressed as follows.

First, Applicants make note of the objection to the Information Disclosure Statement filed on May 26, 2008. In the Office Action, Applicants were given a period of one month to submit references that were cited in the Search Report, but not listed in the IDS. Applicants submitted those references in an IDS on April 3, 2008. Therefore, Applicants request that the references be considered.

### Objection to Specification

The specification was objected to for including trademarks that were not indicated by capitalization, ® or TM designations, and generic terminology. This objection has been met by the amendments set forth above. Applicants also note that generic descriptions of the trademarks are present on page 9, line 26 through page 10, line 19 of the specification.

### Claim Objections

Claim 32 was objected to for including bulleting of indented material, which the Examiner notes may affect formatting at the time of printing. This objection has been met by removal of the indentations and use of semi-colons to separate the groups previously separated by

indentation, consistent with the Examiner's suggestion. Similar amendments were made to claims 35 and 43.

Claim 42 was objected to for including the phrase "to fixable to the layers." This phrase has been replaced with "fixable to the layers." Applicants thus request that this objection be withdrawn.

#### Double Patenting

The Examiner advised that, should claims 3-6 be found allowable, then claims 21-24 will be objected to as being substantial duplicates thereof. In response, Applicants note that claims 3-6 define the type of hyaluronic derivative present in the in matrix (A), while claims 21-24 define the type of hyaluronic acid present in the external layer(s) (B). Therefore, claims 3-6 and 21-24 are drawn to separate and distinct subject matter, and this rejection may be withdrawn.

#### Rejections under 35 U.S.C. § 112, second paragraph

Claims 1, 3-6, 14, 16, 17, 19-24, 32-34, 37, 39, 42, 44-53, 61, and 63 were rejected for indefiniteness, on the basis that there is not antecedent basis for the term "the inner matrix" in claim 1. This rejection has been met by the present amendment to claim 1, by which the multilayer composite is now specified as comprising (A) an inner matrix, which is a composite material and comprises (i) hyaluronic acid or a hyaluronic acid derivative, and (ii) a matrix of demineralised bone and/or biocompatible and biodegradable ceramics and/or bone of autologous or allogenic or animal origin, and (B) one or more external layers superimposed on said inner matrix.

Claim 14 was rejected on the basis that the terms "hydroxyapatite and/or tribasic calcium

phosphate” are redundant for being alternate names of a single chemical species. In response, Applicants submit that hydroxyapatite is not a synonym of tribasic calcium phosphate but, on the contrary, it is a synonym of **hydrated** tribasic calcium phosphate, having the CAS registry number indicated by the Examiner namely [12167-74-7], and characterized by the general formula  $[\text{Ca}_5(\text{OH})(\text{PO}_4)_5]_x$ . However, another type of tribasic calcium phosphate exists, namely the **anhydrous** form, having a different CAS registry number, [7758-87-4], and characterized by the formula  $\text{Ca}_3(\text{PO}_4)_2$  (See Enclosure 1). It was for this reason that Applicants mentioned the two different species in the alternative. To better differentiate these terms, claim 14 has been amended by insertion of the word “**anhydrous**” before “tribasic calcium phosphate.”

Claims 19 and 20 were rejected on the basis that it is not clear which layers of claim 1 the reference to layers in claims 19 and 20 refers. This rejection has been addressed by the amendment to claim 1, in which the wording “in association with at least one layer” was replaced with “(B) one or more external layers comprising a hyaluronic acid derivative superimposed on said inner matrix.” In view of this amendment, it is clear which layers these claims refer to.

Claims 19 and 20 were also rejected for including the phrases “wherein the layers are 2” and “wherein the layers are 3,” which have been replaced with “comprising 2 external layers (B)” and “comprising 3 external layers (B),” respectively.

Claim 3 was rejected for including the phrase “with a percentage,” which has been deleted from this claim, as well as claim 21.

Claim 33 was rejected for including the term “2-dimensional structure,” which has been removed from the claim, with the understanding that this does not change the scope of the claim.

Claims 34, 37, 39, and 53 were rejected for including abbreviations HA, ACP, BMP, TGF, PDGF, FGF, EGF, IGF, and VEGF. These abbreviations have been replaced with the

corresponding full words. No new matter has been added, as the added material is well known in the art to correspond to the prior abbreviations. Support for this understanding can be found, for example in the enclosed Exhibit 2.

Claim 16 was rejected for including different variants of kD. This rejection has been met by amendment of this claim to use the term “KD,” which is consistent with the remainder of the specification.

Claim 36 was rejected for including the trademark/trade name ACP®. This rejection has been met by addition of the ® to the claim. Applicants further note that generic terminology for ACP® is provided previously in the application (see above).

#### Rejections under 35 U.S.C. § 103(a)

Claims 1-17, 19-34, 37, 39, 42-53, 61, and 63 were rejected for obviousness over Valentini, U.S. Patent No. 5,939,323. This rejection is respectfully traversed, for the following reasons.

In response, Applicants first note that, in contrast to the Examiner’s characterization, the claims are **not** drawn to a multilayer composition, comprising an inner matrix of a HA derivative and a matrix in association with a hyaluronic acid derivative. Rather, the claims specify a **multilayer** composite material, comprising:

- (a) an inner matrix containing (i) hyaluronic acid or a hyaluronic acid derivative, and (ii) a matrix of demineralised bone, and/or biocompatible and biodegradable ceramics, and/or bone of autologous or allogenic origin, and
- (b) one or more external layers comprising a hyaluronic acid derivative superimposed on said inner matrix

The specific three-dimensional scaffold of the present invention, as specified in amended claim 1, is neither disclosed in Valentini nor would the skilled person be able to infer it and conclude that it could be advantageously used for bone tissue regeneration, especially in the field of spinal surgery, and in particular for surgical operations, involving the fusion of two vertebrae from the generic teaching disclosed by Valentini.

Valentini at most teaches three-dimensional **porous** scaffolds formed by hyaluronic acid derivatives, including a benzyl ester having various esterification degrees on the hyaluronic backbone (see column 1, lines 65-67).

It also contemplates two-phase scaffolds, in which the second component may be PGA, PLLA hydroxyapatite, or calcium triphosphate. However this two-phase material does not contemplate the presence of a further layer. In fact, as is clearly shown in the examples, and in column 6, lines 47-55, the two-phase scaffold of Valentini is used **as an alternative to coating**, which moreover according to Valentini is carried out by applying a film to a scaffold made of the **sole hyaluronic acid derivative**, coating which according to Valentini may consist **indifferently** of HYAFF, PLLA, and PGA (see column 10, indent 2f).

It follows, therefore, that, based on Valentini, the skilled person would be led away from the presently claimed invention, a multilayer composite material, formed not only by a two-phase matrix, but also containing one or more layers superimposed on said matrix.

In addition, the coating technique allows obtaining the application of a thin film, whereas the layer contemplated for the claimed invention may **also** be in the form of non-woven material, or compact and perforated membranes.

It follows, therefore, that the generic teaching of Valentini was decidedly far from directing the skilled person to the specific material as specified in claim 1 of the present

application, even more so the skilled person would be unable to gain from Valentini any valid teaching addressing him towards the use of said scaffolds in the spinal surgery. In view of the above, Applicants request reconsideration and withdrawal of the obviousness rejection over Valentini.

#### CONCLUSION

Applicants submit that the claims are in condition for allowance, and such action is respectfully requested. If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: September 26, 2008

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Reg. No. 42,885

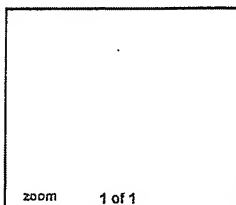
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ENCL. 1

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and availability information?[Click Here](#)**C3161 Calcium phosphate tribasic**

Sigma

plant cell culture tested, powder



## Synonym

Calcium hydroxyphosphate

HAp

Hydroxylapatite

## Molecular Formula

 $[\text{Ca}_5(\text{OH})(\text{PO}_4)_3]_2$ 

## Molecular Weight

502.31

## CAS Number

12167-74-7

## MDL number

MFCD00010604

## PubChem Substance ID

24892590

## EG/EC Number

235-330-6

zoom 1 of 1

[Expand/Collapse All](#)**Price and Availability**[Click For Pricing and Availability](#)**Descriptions**Other Notes Approx.  $\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$ 

Preparation Note Precipitated to reduce trace impurities.

**Properties**

form powder

solid

mp 1100 °C(lit.)

suitability plant cell culture tested

**References**

reference Corp MSDS 1 (1), 670:A / FT-IR 2 (3), 4742:A / FT-IR 1 (2), 1267:C / RegBook 1 (3), 3425:C

**Safety**

Hazard Codes Xi

Risk Statements 36/37/38

Safety Statements 26

WGK Germany 3

**Related Categories**

... Inorganic Salts &gt; Calcium

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Information Sheet (25kb)

MSDS

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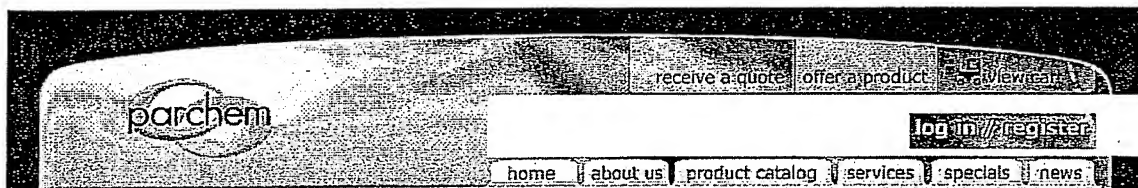
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## Calcium Phosphate tribasic anhydrous

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Product: Calcium Phosphate tribasic anhydrous  
CAS: 7758-87-4  
Synonym: Calcium Phosphate Tribasic  
Formula:  $\text{Ca}_3(\text{PO}_4)_2$   
Class: Chemicals: Inorganic  
Product Type:  
Hazard:

## SPECIFICATIONS

Description: Tri Calcium Phosphate is a generic name for the pr  
Molecular Weight (theoretical): 502  
Sensoric: White powder  
Taste: Tasteless  
Odour: Odorless  
Solubility (grams/100 gram water) at 0°C: (gr/100 ml at 25°C) :In Water : Almost Soluble  
Identification: Meets FCC tests  
Assay %: (as Ca) : 34 - 40 %  
Loss on Ignition (550°C): (800 °C) : 10 % Max  
Heavy Metals, as Pb: 5 ppm Max  
Lead: 0.5 ppm Max  
Flouride: (as F) : 10 ppm Max  
Arsenic PPM: 1 ppm Max  
Acid Insoluble matter: 0.1 % Max  
Bulk Density: (gr/ml) 0.23 - 0.5

## Notes:

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
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
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






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**PDGF**

platelet-derived growth factor; interacting with cell surface receptors and stimulating hydrolysis of inositol 1,4,5-triphosphate (IP<sub>3</sub>).

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














































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
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




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The three-letter abbreviation FGF may stand for:

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



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Several studies now under way or due to begin soon will also assess the effects in humans of FGF proteins and the genes that encode them, he says, perhaps shedding light on these questions.  
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Some immunoreactivity for the FGF type 1 receptor in the extracellular matrix of leiomyomas has been demonstrated, although the cellular staining for the receptor was greater in the myometrium than in the leiomyomas (Anania et al.  
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
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- [European Genetics Foundation](#), a training organization for geneticists
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